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Incorporating Patient-Safe Design into the Guidelines

Abstract | **Article**

The Guidelines for Design and Construction of Hospital and Health Care Facilities (Guidelines) is used by many jurisdictions across the U.S., in whole or in part, as a regulation defining minimum building design standards for various types of healthcare facilities. First published as part of the Hill-Burton program in 1947, the document has gone through many revisions and changes in scope and purpose before arriving at its present place as a national standard. The Guidelines contain information about many aspects of the healthcare facility environment, but to date has neither information nor requirements related to patient-safe design. Including a patient-safe design requirement into the Guidelines would offer a minimum-force function into the design and construction of healthcare facilities. This change is essential in the current environment in which healthcare facilities are rapidly constructed with little to no explicit regard to preventing patient harm by safe design.

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People, Not Procedures**

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Background on Patient Safety

In 1999, the Institute of Medicine (IOM) released its seminal report, *To Err is Human*, on the state of healthcare in America. The central finding of the report was that between 44,000 and 98,000 Americans die in hospitals every year due to preventable errors, mistakes, and accidents.¹ The report also noted that the number of permanently disabling injuries resulting from mistakes and accidents is twice the number of deaths. This revelation resulted in a flurry of news reports and articles about the subject, but the issue has now faded from public consciousness. In a report issued the following year, the IOM further refined its suggestions for addressing the problem and chastised the American medical community for its lack of progress.² The community of healthcare facility designers cannot avoid sharing this criticism.

To Err is Human included descriptions of these essential concepts:

- ***Errors should be considered systemic problems, not the fault of single individuals.***
- ***Systems are composed of components, which are based on human performance, technology, the physical environment, and clinical processes.***
- ***Errors should be scientifically studied by gathering data and performing analyses to determine their root causes.***
- ***The environment does contribute to errors and adverse patient outcomes.***

We add one proposition to these:

- ***The scientific study of error requires a collaborative, multidimensional effort that must include professionals from a number of knowledge community spheres.***

While the IOM report mentions environmental factors as potential contributors, it appears to define “environment” in terms that give it a scope beyond that which architects and engineers would consider. The IOM did not give specific examples or statistics indicating the extent of mistakes, errors, or accidents that may have an environmental contributor. The lack of research and data

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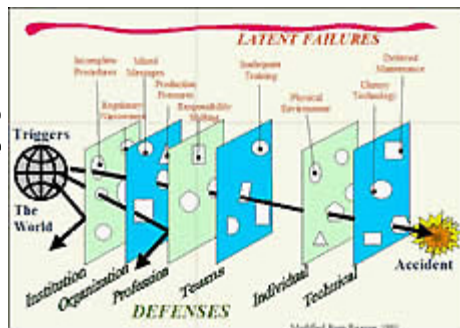
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on this subject, however, does not diminish the fact that many experienced healthcare facility design practitioners can conceive of causal relationships between physical environment factors and human errors that affect patient safety.³

An error is “the failure of a planned sequence of mental or physical activities to achieve the intended outcome when these failures cannot be attributed to chance.”⁴ British psychology professor James Reason, in his “Swiss cheese” model, describes holes in a system’s defenses that are created by dormant elements (latent errors) of the system (Figure 1).⁵ When the holes line up, they allow an error vector to pass through and harm the patient. A simple example will clarify this point. In many hospitals the operating room (OR) and the intensive care unit (ICU) are not on the same floor, which prolongs the patient transfer from the OR to the ICU and creates opportunities for information to be lost and for failed patient hand-offs. Because of this ubiquitous design, emergency interventions occasionally need to be conducted in corridors or elevators, a situation conducive to patient harm. A more patient-safe design could minimize those unnecessary risks.



The Swiss-cheese model of adverse event causation
(Modified from James Reason, 1991)

We believe that the environmental contribution to errors and harm is significant, although not always direct. For example, the IOM report states that medication errors are one of the most prominent types of errors and patient harm and cites causes including

- Poor handwriting or misinterpretation of names
- Misinterpretation of dose or mislabeling
- Contamination during preparation
- Selection of wrong medication for administration due to a similar label (sound-alike or look-alike) or misplacement of supply
- Misidentification of the patient and administration to the wrong patient.

At first glance, most of these appear to be human errors, pure and simple. When they are analyzed as part of a system, however, we are forced to examine all conditions that may be enabling the accident to occur. In detailed root-cause analysis, it becomes apparent that some errors may have been caused by environmental factors such as

- Poor lighting quality and quantity
- Distracting noise
- Inadequate space, poor ventilation, poor selection of finishes
- Poor layout of medication area or system

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Poor graphics /room /patient identification.

All physical environments have a large number of characteristics and qualities. Some of these relate to the environment in its entirety and some to its subcomponents. For example, we may quantify a space by its size or volume. Or we may look at the degree of contrast between the floor and wall finish at a particular location; that is an aspect of subcomponents, or more exactly two of them. We could describe the airflow pattern in a room, lighting levels at various places in the room, or the coefficient of friction of the flooring. We believe that many of these characteristics will ultimately be demonstrated through peer-reviewed research to be both relevant and causative with respect to adverse events. For example, smooth terrazzo floors on geriatric patient wards might be aesthetic and easy to maintain, but ultimately will be found to contribute to patient falls. Common sense leads to the conclusion that these systems and human factors must be considered during the design of healthcare facilities.

We caution that reliance on technology alone to solve human errors related to patient safety is a grave oversight. A recent article in the Journal of the American Medical Association found that a first-generation computerized physician-order entry system created 22 new error possibilities. New technologies operate in new or existing environments with their latent error-contributing conditions. Unfortunately, new technologies may fail in the same way as older ones, but with even greater damage. Figure 2 shows how old and new technologies are prone to similar problems of imbalance when safe systems are not in place to counter these dangers.



Figure 2. Old and new technologies leading to adverse events.

History of the Guidelines

The Guidelines for Design and Construction of Hospital and Health Care Facilities (Guidelines) is the single most referenced document by healthcare design professionals.⁶ The American Institute of Architects now owns the intellectual content of the Guidelines. The rights have been

assigned to the Facilities Guidelines Institute (FGI), which is charged with maintaining the publication, undertaking periodic revisions, and promoting and funding research related to the standards contained in the document. While the Guidelines have been widely adopted by Authorities Having Jurisdiction (AHJ),⁷ there are divisions in the architectural community as to whether the book should be a guideline, as indicated by its title, or a regulation, which has become one of its primary functions. Because the purpose of the book has not been resolved, it contains both material that speaks to the minimum acceptable standards for a facility (regulatory) and material that speaks to desirable and even ideal facility design (guidance). For the most part, this duality has been handled by placing the guidance in appendices that are presented in a commentary form that follows the core material.

Those involved in editing and revising the Guidelines have attempted to keep operational material out of the document, although there are intersections between design and operations. An example is the requirement for an infection control risk assessment (ICRA) to be a part of every healthcare project. The ICRA involves design and construction entities and operational entities as necessary parts of its development and execution. It envisions a seamless situation where, unfortunately, seams may be sharply drawn.

Proposed Solution

We have described a problem: major adverse events occur to patients due to poorly designed systems coupled with human errors. We argue that this problem has built-environment contributors. We have described a professional publication that has universal recognition among the ownership, regulatory, design, and construction segments of the industry. Now we will make the case that we need to embrace the opportunity to advance healthcare-facility building development and design that will enhance patient safety.

How does one approach the design of a healthcare facility to make it safe?

While there is no single answer to this question, there are characteristics of the solution process that are apparent. These characteristics are based on the nature of the information to be collected and analyzed and the experience of others from different knowledge domains attempting to improve patient environments. We believe these characteristics are the following:

- The process should be collaborative. It should incorporate the disciplines, knowledge bases, and methodologies of all spheres of learning and experience that are relevant to safe healthcare design.**
- The process should be scientific. It should be conducted according to scientific standards with documented, measured, and shared results that can be replicated by others.**

The process should start at the onset of the project, before major assumptions have been made. It should allow the consideration and validation of all aspects of the project, from clinical and other operating processes to staffing/human resources and the selection of equipment and design details.

- **The process should guide the design, not the design guide the process. To be effective, patient-safe design must be surrounded by the concept of a patient-safe culture.**

Another key issue is how patient-safe design can be incorporated as a concept into the Guidelines, given that:

- **Precise methodologies and metrics are yet to be developed**
- **The scope and types of projects covered in the Guidelines are quite extensive**
- **Radical departures from current norms may be rejected out of hand.**

There are three approaches to this problem. The first would be to write a detailed prescriptive section using the current best thinking on the subject. This approach would include problem definitions, step-by-step guidance, and descriptions of analytical methods, such as failure-mode effects analysis and root cause analysis. It would also include accurate measurement and data-sharing techniques. This prescriptive approach is well-suited for adoption as regulatory language. It gives clear direction and describes the intended result. This approach would level the playing field for regulators, planners, and designers. The difficulty with a prescriptive approach is also one of its virtues—that is, it is rigid. There would be limited latitude for AHJs and designers to incorporate new techniques or to deal with previously unrecognized conditions.

A second approach would be to treat this subject in an informational way. This would include adding language to the appendices of the Guidelines that describe the problem of human error, adverse events, and the causal relationship between the built environment and patient safety. This approach would inform the regulatory, ownership, and design communities without placing additional burdens on them.

The final approach, which the authors recommend, would be to place a requirement in the Guidelines similar to that for ICRA. The requirement would describe a flexible process that can be modified for a range of situations. The process would not have a fixed number of anticipated studies or results, but would require a systematic, documented consideration of patient-safety concerns during the planning and design process. The requirement would include the explicit formation of a team composed of disciplines and resources suited to address these issues. The team would determine a plan for investigating patient-safety challenges based on data furnished by the institution and national safety priorities. Where proposed solutions might conflict with codes or regulations, this approach

would require that the conflicts be vetted with the appropriate agencies and their decisions noted. The transparency of this process will help the community of healthcare regulators, owners, and designers rapidly learn these lessons. Solutions of workflow redesign or personnel changes would be referred to the appropriate institutional departments for evaluation and action.

The challenge of this approach is that it could be interpreted in a number of ways, no matter how clear the language. For example, the ICRA language in the 2001 edition of the Guidelines illustrates this. Controversy developed over the intentions of paragraph 5.1 with respect to professional liability for the ICRA study and whether the language in the third paragraph, “panel with expertise in . . . facility design,” was intended to require participation by the architect of record. There was also controversy over the language in the fourth paragraph that required that “the design professional shall incorporate the specific, construction-related requirements of the ICRA in the contract documents.” The problem was the liability assumed by the design professional over information provided by others. The proposed solution to this problem was to revise the language of paragraph 5.1 to clarify the composition of the team and to place the requirement for incorporation on the project owner, where it most belongs.

We recognize that the language to be incorporated as a patient-safe design process into the Guidelines will need to be modified as we learn more about designing safe healthcare environments. By providing flexibility and by utilizing the Interpretations Committee’s review process (a part of the FGI), we believe the impact of these limitations can be minimized. We also believe that by making this proposal through The Academy Journal of the AIA Academy of Architecture for Health, a large number of interested persons who are involved in healthcare facility design will have an opportunity to comment and present other solutions or reasoned objections.

Endnotes

1 Institute of Medicine. *To Err is Human: Building a Safer Health System*. Washington, D.C.: National Academy Press. 2000.

2 _____. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, D.C.: National Academy Press. 2001.

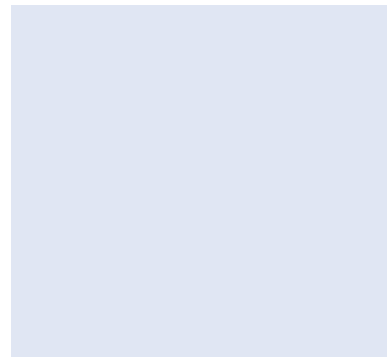
3 The Center for Health Design. *The Role of the Physical Environment in the Hospital of the 21st Century: A Once-in-a-Lifetime Opportunity*. Ulrich, Roger, et al.

4 _____. *To Err is Human: Building a Safer Health System*. Washington, D.C.: National Academy Press. 2000.

5 Reason, James. *Human Error*. Cambridge, U.K.: Cambridge University Press. 1990. Illustration has been modified from original form.

6 *The American Institute of Architects Academy of Architecture for Health, The Facilities Guidelines Institute, et al. 2001 Edition Guidelines for the Design and Construction of Hospital and Health Care Facilities. Washington, D.C.: The American Institute of Architects. 2001.*

7 *The regulatory official who is vested with power to approve the design of a healthcare building.*



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